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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,339	01/26/2004	Shawn R. Feaster	034047.003DIV1 (W 00-23B)	7108
53502 7590 05/09/2011 OFFICE OF THE STAFF JUDGE ADVOCATE (SKS) U.S. ARMY MED. RESEARCH & MATERIEL COMMAND 504 SCOTT STREET ATTN: MCMR-ZA-J (MS. ELIZABETH ARWINE) FORT DETRICK, MD 21702-5012				
EXAMINER				
SIEN, BIN				
ART UNIT		PAPER NUMBER		
1653				
MAIL DATE		DELIVERY MODE		
05/09/2011		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/763,339

**Applicant(s)**

FEASTER ET AL.

**Examiner**

BIN SHEN

**Art Unit**

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 March 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29-36 and 39-43 is/are pending in the application.
- 4a) Of the above claim(s) 31-34 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29, 30, 35 and 39-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 29-36, 39-43 are currently pending. Claims 31-34, 36 are withdrawn from further consideration.

Claims 29, 30, 35, 39-43 are presented for examination on the merits.

### ***Priority***

This application is a DIV of 09/848,371, PAT 6746850 (filed on 05/04/2001), which claims benefit of 60/202,201 (filed 5/5/2000).

### **Withdrawal of Rejections:**

In view of amended claims and applicant's arguments, the rejection under 35 USC §112-2<sup>nd</sup> paragraph is hereby withdrawn.

In view of amended claims and applicant's arguments, the rejections under 35 USC §102(b) over London, 103(a) rejection over London and Jacobs are hereby withdrawn.

### **New Rejections due to amendment to claims:**

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29, 30, 35, 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over **London** (Occupational and Environmental Medicine, 1995, 52: 57-64), in view of **Worek** (Clinica Chimica Acta, 1999, 288:73-90), and **Jacobs** (CLIN. CHEM., 1993, 39(9):1890-1893).

London, throughout the reference teaches a field kit (Test-Mate OP kit) for estimation of cholinesterase in whole blood using two substrates: butyrylthiocholine and acetylthiocholine (in reagent dispenser, page 59, left column, 2<sup>nd</sup> full paragraph). For details of the Test-Mate OP kit and what is in the reagent dispenser see Magnotti, 1988, page 317, 3<sup>rd</sup> and 4<sup>th</sup> full paragraph, and page 318, step2 of "Field kinetic method").

For **claim 29**, the reference teaches a device for detecting, measuring or monitoring cholinesterase in blood sample comprising **a cartridge** (read as reagent dispenser) with substrate (page 59, left column, 2<sup>nd</sup> full paragraph, lines 1-3); **a detector** for detecting reaction rates (colorimeter, page 59, left column, 2<sup>nd</sup> full paragraph, line 5); **software** for calculating protein concentration (page 59, left column, 2<sup>nd</sup> full paragraph, line 5);

For **claim 30**, the reference teaches the cartridge/kit comprises reagent, buffer standard for measuring the reaction rates (see substrate for the enzymes on page 59, left column, 2<sup>nd</sup> full paragraph, lines 1-3, since the field kit estimate cholinesterase therefore inherently contains all necessary reagent/buffer/standard for measuring the reaction rates;

For **claim 35**, the reference teaches the kit is capable of detecting cholinesterase including plasma cholinesterase and erythrocyte cholinesterase (plurality of proteins, page 59, left column, 2<sup>nd</sup> full paragraph, lines 1-2);

For **claim 39**, the reference teaches the field kit (Test-Mate OP kit, page 57, right column, 3<sup>rd</sup> full paragraph, lines 8-9) is inherently hand-held for easy application;

For **claim 42**, the reference teaches a device for detecting, measuring or monitoring cholinesterase in blood sample comprising **a cartridge** (read as reagent dispenser) with substrate (butyrylthiocholine or acetylthiocholine); **a detector** for detecting reaction rates (colorimeter, page 59, left column, 2<sup>nd</sup> full paragraph, line 5); **software** for calculating protein concentration (page 59, left column, 2<sup>nd</sup> full paragraph, line 5);

For **claim 43**, the reference teaches a device for detecting, measuring or monitoring cholinesterase in blood sample comprising **at least one substrate** (butyrylthiocholine or acetylthiocholine); **a detector** for detecting reaction rates (colorimeter, page 59, left column, 2<sup>nd</sup>

full paragraph, line 5); **software** for calculating protein concentration (page 59, left column, 2<sup>nd</sup> full paragraph, line 5).

London does not explicitly teach at least two substrates in the cartridge as recited in **claims 29, 41- 43**, cartridge triggers device automation when inserted as recited in **claim 40**.

However, **Worek**, throughout the reference teaches determination of acetylcholinesterase (AChE) activity in human blood with two different substrates (acetylthiocholine-ASCh and s-butyrylthiocholine-BSCh, page 77, Table 1, as recited in **claims 29, 41- 43**); and the advantage of their approach is to provide a simple way for sensitive and precise determination of AChE activity in whole blood in the presence of organophosphates even with low-tech equipment (abstract, page 73, lines 11-13), a robust procedure for estimating AChE activity in whole blood with simple filter photometers, also allowing the detection of small activities of AChE in whole blood of intoxicated patients, the method also give reliable results in the presence of inhibitor and reactivator (last line of page 74 to page 75, top lines 1-3)

In addition, **Jacobs** teaches a blood analyzer with an insertable cartridge (page 1891, left column, 1<sup>st</sup> full paragraph, **claim 40**).

Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to modify the device of London by using at least two substrates in the cartridge, and make it a insertable cartridge.

A person of ordinary skill in the art would have been motivated at the time of the invention to modify the device of London by using at least two substrates in the cartridge, because both London and Worek teach determining cholinesterase activity and Worek teaches the advantages of using two different substrates for simple, sensitive, precise determination of AChE activity in whole blood that reduces the interference of inhibitor/reactivator that presence in the blood sample.

A person of ordinary skill in the art would have been motivated at the time of the invention to modify the device of London by using an insertable cartridge, because both London and Jacobs teach blood analyzer and Jacobs teaches the use of an insertable cartridge for fast and easy point-of-care testing.

An ordinary skilled artisan would have reasonable expectation of success of achieving such modifications because all of the cited references teach the various components of the

device/assay including using different substrates and using insertable cartridge to improve the device for fast/simple/sensitive/precise analysis.

### ***Conclusion***

Claims 29, 30, 35, 39-43 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sue Liu can be reached at (571) 272-5539.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*B Shen*

Art Unit 1653

/SUE LIU/

Supervisory Patent Examiner, Art Unit 1653